Atty Docket No. SHD-002-USA-P

REMARKS

Claims 1-3, 5-12, 16-17, 19 and 21 have been cancelled, and claims 4, 13-15, 18, 20 and 22 have been amended to more definitely set forth the invention and obviate the rejections. Support for the amendments to claims 4, 13-15, 18, 20 and 22 can be found in the Specification on page 2, second to last paragraph, Examples 1-4 in the Specification, Table 2 on page 10, and in the now cancelled claims herein. The present amendment is deemed not to introduce new matter. Claims 4, 13-15, 18, 20 and 22 remain in the application.

Reconsideration is respectfully requested of the objection to claims 1 and 3-4.

Claims 1 and 3 have been cancelled herein. Further, claim 4 has been amended to correct the spelling of "processing". In view of same, it is believed that the objection is now moot. Withdrawal of the objection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of Claims 1-7 and 8-22 under 35 U.S.C. 103(a) as being unpatentable over Lentini, et al. (WO 11/33803) and Katsuhiro (JP 01-165517) in view of Tanaka (USP 5,540,921).

The primary Lentini, et al. reference teaches a sunscreen composition comprising a fluororesin having a submicron in combination with a sunscreen agent and an oil component. Specifically, Lentini, et al. teaches a less irritating sunscreen product, achieved by reducing the amount of sunscreen agent such as octylmethoxy cinnamate, and other sunscreen agents such as TiO_2 (see USP '156, column 5, lines 1-4). Unlike the present invention, reduction in skin irritation is achieved by using a *fluorinated polymer powder (e.g., fluororesins powder, such as TEFLON powder)*. Lentini, et al. teaches that such fluorinated polymer powders boost the SPF

(sun protection factor) of the sunscreen agent, which is achieved by strengthening the sunscreen effect of sunscreen agents such as octylmethoxy cinnamate. Because sunscreen agents (such as octylmethoxy cinnamate) strengthen the sunscreening ability via the fluorinated polymer powder, the content of the sunscreen agent such as octylmethoxy cinnamate caused of irritation can be lowered, and the formulation can have a low irritation characteristic.

As previously submitted, and as the Examiner has recognized on page 4 of the instant Office Action, Lentini, et al. fail to teach or suggest the hydrophobically treated zinc oxide powder, as claimed herein. In addition, as the Examiner has also again recognized on page 4 of the instant Office Action, Lentini, et al. further fails to disclose the use of a glucoside as claimed herein. As shown above, the claims have been amended herein to now specifically call for only a method and process of reducing skin irritation caused by the presence of octylmethoxy cinnamate *when blended with powders of titanium oxide and zinc oxide* in a skin cosmetic specifically by adding a specific amount of a glucoside *not taught by Lentini, et al.* to the cosmetic composition containing octylmethoxy cinnamate.

In contrast to the cited Lentini, et al. reference, the present invention does not intend to use fluororesin powders, such as TEFLON® powder, for the purpose of reducing irritation, and octylmethoxy cinnamate and ZnO can be included in the composition without reducing the amount of same to avoid skin irritation. This important feature of the present invention is not taught or suggested by Lentini, et al.

The present inventors have found that a given amount (even a small amount of) octylmethoxy cinnamate, which does not cause irritation when applied alone, causes irritation to the skin if it is mixed with the powders of zinc oxide or titanium oxide (see Specification, page

2, line 15 to 22). Although octylmethoxy cinnamate alone may not cause irritation alone, the present inventors found that mixing same with powdered zinc oxide or titanium oxide produces significant irritation. However, the present inventors have unexpectedly discovered through comparative testing (the results of which are shown in Table 2 of the Specification) that adding from 2-15 wt% of POE or POP methyl glucoside to a composition containing octylmethoxy cinnamate and powdered titanium oxide and zinc oxide greatly reduces or eliminates such irritation to the skin.

In order to cure the deficiencies of Lentini, et al., the Examiner has again cited the Katsuhiro, et al. reference. Katushiro, et al. disclose a cosmetic agent comprised of TiO_2 and POE methyl glucoside, for use as a sunscreen formulation. However, Katsuhiro, et al. fail to address the issue of irritation caused by application to the skin of a cosmetic composition comprised of *octylmethoxy cinnamate and powdered ZnO*, and the use of POE methyl glucoside as a component in an external skin preparation containing same, which acts as an agent capable of reducing the irritation caused by octylmethoxy cinnamate with ZnO. Further, unlike the present invention, Katsuhiro, et al. fail to teach or suggest that by adding *2-15 wt% of* POE methyl glucoside to a external skin preparation comprising octylmethoxy cinnamate and hydrophobically treated ZnO, as now claimed herein, the amount of the sunscreen agents can be maintained without an increase (and even with a decrease) in skin irritation. Rather, these teachings come only from the present invention, and constitute an important element or aspect thereof.

The secondary reference of Tanaka discloses a solid oil-in-water cosmetic composition. As the Examiner has stated, Tanaka does teach a zinc oxide powder, and the possible

hydrophobic treatment thereof. However, like both Lentini, et al. and Katsuhiro, et al. discussed above, it is believed that Tanaka likewise fails to address the issue of skin irritation caused by application to the skin of octylmethoxy cinnamate with powdered ZnO, and overcoming same *by adding 2-15 wt%* of POE methyl glucoside to an external skin preparation comprising octylmethoxy cinnamate and hydrophobically treated ZnO. Rather, that teaching comes only from the instant application, and constitutes an important element or aspect of the present invention.

Office personnel should consider all rebuttal evidence that is timely presented by the applicants when reevaluating any obviousness determination. Rebuttal evidence may include evidence of "secondary considerations" such as commercial success, long felt but unsolved needs [and] failure of others, and may also include evidence of unexpected results. Federal Register Notice, volume 72, October 10, 2007, at 57534.

Although the Supreme Court recently rejected the requirement that there must be some teaching, suggestion or motivation in the prior art that would have led one of ordinary skill in the art to modify the prior art references to arrive at the claimed invention, the Court nonetheless indicated that the lack of any teaching, suggestion or motivation in the prior art may still be considered as one factor in the overall determination of obviousness. *KSR International Co. v. Teleflex, Inc.*, 550 U.S. _____ , 82 USPQ 2d 1385 (2007)

With respect to the second issue above, objective evidence of secondary considerations, such as unexpected results, are relevant to the issue of obviousness and must be considered in every case in which they are present. See MPEP 2141 II. It is the duty of the Examiner to evaluate such evidence. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871

(Fed.Cir., 1983); and *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed.Cir., 1986), cert. denied, 480 U.S. 947 (1987).

Proof of an unexpected improvement can rebut a prima facie case of obviousness. *In re Murch*, 464 F.2d 1051, 175 USPQ 89 (CCPA, 1972). No matter how strong the prima facie case of obviousness made out by the PTO, it must be weighed against any factors to the contrary brought out by the applicant in determining the validity of the conclusion of patentability unobviousness. *In re Lewis*, 443 F.2d 489, 170 USPQ 84 (CCPA, 1971). Therefore, facts established by rebuttal evidence must be evaluated along with the facts on which the conclusion was reached, not against the conclusion itself. *In re Lilly & Co.*, 902 F. 2d 943, 14 USPQ 2d, 1741 (CAFC, 1990).

Conventionally, the amount of sunscreen agents such as octylmethoxy cinnamate and zinc oxide must be reduced so as to reduce skin irritation. However, in contrast to the Lentini, et al., Katsuhiro, et al. and Tanaka references cited herein, it is respectfully submitted that the present inventors unexpectedly discovered, *as clearly demonstrated by the comparative test data shown in the Specification*, that skin irritation caused by application to the skin of a sunscreen composition comprised of octylmethoxy cinnamate with powdered ZnO (zinc oxide) can be overcome by adding POE methyl glucoside to the sunscreen composition, *without* a concurrent reduction in the amount of the sunscreening agents.

In particular, tests were performed to determine the effectiveness of the claimed glucoside and, as described in the "continuous skin irritation test" section on pages 7-11 of the instant Specification, it was unexpectedly discovered that by adding *2-15 wt%* of the glucoside (namely POE methyl glucoside) claimed herein to a sunscreen composition comprising

octylmethoxy cinnamate and ZnO, the skin irritation caused by the combination of these components is reduced or eliminated.

With regards to the Examiner's "Response to Arguments" section, bridging pages 5 and 6 of the instant Office Action, the Examiner appears to be implying that Lentini, et al. teaches or suggests the method or process of reducing irritation to the skin caused by octylmethyl cinnamate. Although Lentini, et al. do discuss same, *they do NOT teach the use of a glucoside, or the particular weight range of same*, as claimed herein, in performing this function. Further, it is believed that none of the cited secondary references cure this deficiency. Rather, that teaching or suggestion is believed to come only from the present invention, and constitute an important element or aspect thereof.

Accordingly, it is again strenuously urged that the evidence of unexpected results rebuts any prima facie case of obviousness in the instant rejection. Furthermore, the claims have been amended herein to be commensurate in scope with the demonstrated unexpected results. Consequently, it is believed that the Examiner would now be justified in no longer maintaining this rejection. Withdrawal of the rejection is accordingly respectfully requested.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early action and allowance thereof is accordingly respectfully requested. In the event there is any reason why the application cannot be allowed at the present time, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems.

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Respectfully submitted,

TOWNSEND & BANTA

Donald E. Townsend, Jr.

Donald E. Townsend, Jr.
Reg. No. 43,198

Date: May 18, 2009

TOWNSEND & BANTA
Suite 900, South Building
601 Pennsylvania Ave., N.W.
Washington, D.C. 20004
(202) 220-3124

CUSTOMER NO. 27955

CERTIFICATE OF TRANSMISSION

I hereby certify that this 11-page Amendment After Final, in patent application Serial No. 10/671,519, filed September 29, 2003, is being facsimile transmitted to the United States Patent and Trademark Office (Fax No. 571-273-8300) on May 18, 2009.

Donald E. Townsend, Jr.

Donald E. Townsend, Jr.